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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,065	05/05/2005	Hector F Deluca	1256-01012	1544

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ANDRUS, SCEALES, STARKE & SAWALL, LLP
100 EAST WISCONSIN AVENUE, SUITE 1100
MILWAUKEE, WI 53202

EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,065	DELUCA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-11 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8-11 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/23/2009 has been entered.

Claim(s) 1, 8-11 and 20-22 are pending. Claim(s) 1 has been amended. Claim(s) 1, 8-11 and 20-22 are examined herein.

Response to Arguments

Applicants arguments against the ODP rejection over Application 10/105,826 is not persuasive because Applicant is now arguing based on amended claims, but in view of Applicant's amendments to the claims the ODP rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) obviousness rejection of claims 1, 8-11 and 20-22 as being unpatentable over DeLuca et al. (U.S.Patent No. 5,843,928) hereinafter "Deluca (US)" have been fully considered but found not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended the claims, said rejection is hereby withdrawn.

In view of Applicant's amendments with respect to the 103(a) obviousness rejection of claims 29, 30, 33-35, 44, and 45 as being unpatentable over DeLuca et al. (U.S.Patent No. 5,843,928) of record hereinafter "Deluca (US)", as applied to claims 1, 8-11 and 20-22 above in view of Deluca et al. (WO 02/05823A2) of record hereinafter "Deluca (WO)", and Bockman et al. (U.S.Patent No. 5,556,645) of record, the rejection is hereby withdrawn.

In view of Applicant's amendments with respect to the 103(a) obviousness rejection of claims12-19 and 36-43 as being unpatentable over Deluca (U.S. Patent No. 5,843,928), hereinafter "Deluca (US)", as applied to claims 1, 8-11 and 20-22 above in view of Deluca (WO 97/11053), hereinafter "Deluca (WO)", the rejection is hereby withdrawn.

The office action below sets forth the following rejections as necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the

claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-11 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (WO 02/05823) hereinafter "Deluca WO 02".

DeLuca WO 02 specifically teaches the compound 2-methylene-19-nor-20(S)-1α,25-dihydroxyvitamin D_3 which is a specie that is encompassed by Applicants general formulas I, V and VI (page 3, lines 9-15).

DeLuca WO 02 teaches the instant compound as being useful in the treatment of diseases where bone formation is desired (page 4, lines 5-9). Additionally, Deluca WO 02 teaches that the instant compound has shown increases in the breaking strength (cortical strength) as well as crushing strength (trabecular strength) of the bone. The compound can be used in conjunction with bone replacement procedures such as hip replacements, knee replacements and the like (page 5, lines 3-7).

DeLuca WO 02 teaches that said compound can be administered in dosage amounts of 0.01μg/day to about 10μg/day (page 4, lines 12-13) to patients (page 15, lines 19-25).

DeLuca WO 02 does not specifically teach "improving bone quality following a distraction osteogenesis procedure..."

It would have been obvious to one of ordinary skill in the art at the time of the invention to have known that based on the teachings of DeLuca WO 02, the compound 2-methylene-19-nor-20(S)-1α,25-dihydroxyvitamin D_3 in fact does improve the quality of the bone. As set forth on record above, it is taught that the instant compound increases the breaking strength and the crushing strength of bone. These are obvious parameters that may be employed to assess the quality of bone. The fact that improving bone quality is not specifically taught as occurring following distraction osteogenesis is patentably irrelevant. The fact that the instant compound improves bone quality is the issue at matter and not at which point it is employed procedurally. Having said this, DeLuca WO 02 does teach that compound can be used in conjunction with bone replacement procedures such as hip replacements and knee replacements by way of example. One of ordinary skill in the art would find it within the scope of bone replacement procedures to also consider distraction osteogenesis.

Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca (WO 02/05823) hereinafter "Deluca WO 02" as applied to claims 1, 8-11

and 20-21abive in view of DeLuca (WO 98/41501) of record hereinafter "Deluca WO 98".

Deluca WO 02 is discussed above.

Deluca WO 02 does not teach the compounds in the instant claims with the proviso that R5 is -OY3 and Y3 is selected from the groups consisting of acyl or a hydrocarbyloxycarbonyl.

Deluca WO 98 teaches 2-methylene-19-nor-20(S)-1α,25-dihydroxyvitamin D_3 and the generic formula I in which it is encompassed (page 4, lines 5-10). The R group is taught to be a straight-chain hydrocarbon that may contain additional substituents such as hydroxyl- or protected hydroxyl groups (page 4, lines 19-22).

It would have been obvious to one of ordinary skill in the art at the time the invention to have employed the 2-methylene-19-nor-20(S)-1α,25-dihydroxyvitamin D_3 to improve the bone quality as taught by Deluca WO 02 and also employed those compounds with the hydroxyl group protected. The motivation, Deluca WO 98, teaches that same compound and the protected derivatives thereof. One of ordinary skill in the art would expect with a reasonable degree of success that the OH parent compound would possess the same properties as that of its hydroxyl protected derivatives, in the absence of unexpected results.

Conclusion

Claims 1, 8-11 and 20-22 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617